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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,611	09/29/2003	Robert A. Rousseau	ETH5097	4200
27777	7590	07/27/2006	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			POUS, NATALIE R	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/674,611	Applicant(s) ROUSSEAU, ROBERT A.	
	Examiner Natalie Pous	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/16/04, 1/21/04</u> . | 6) <input checked="" type="checkbox"/> Other: <u>IDS: 3/31/05</u> . |

DETAILED ACTION

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The word "invention" should not be in the abstract. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2, 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haverstock (US 4531521) in view of Haverstock (US 6007564) and further as a matter of design choice.

Haverstock '521 teaches a surgical wound closure/transfer marking device comprising the following:

- a substrate (12) having a proximal surface, a distal surface; an adhesive layer (16) disposed on the proximal surface of substrate and having a first portion (16) and a second portion (29); and a primary release sheet having a proximal surface, a distal surface, a first portion (20), a second portion (32) and where the first and second portions are disposed releasably adherently to the first and second portions, respectively, of adhesive layer
- Wherein the first and second portions of the primary release sheet are detachable from each other
- Wherein the substrate, adhesive layer and primary release sheet are joined in a book-like arrangement (fig. 2)
- The substrate and the adhesive layer are size to substantially conform to each other (fig. 2)

Haverstock '521 fails to teach:

- Markings on the substrate
- markings on the proximal surface of the second portion of the primary release sheet,

- and wherein the markings on the proximal surface of the second portion of the primary release sheet are substantially aligned with the markings on the substrate.

Haverstock '564 teaches wherein the device comprises markings (124) on the substrate, and wherein the markings on the substrate are aligned with markings on the body in order to ensure that the skin is realigned after surgery and the wound closure device is properly positioned. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Haverstock '521 with markings on the substrate as taught by Haverstock '564 in order to ensure that the skin is realigned after surgery and the wound closure device is properly positioned.

The combination of Haverstock '521 and '564 fails to teach wherein markings on the proximal surface of the second portion of the primary release sheet, and wherein the markings on the proximal surface of the second portion of the primary release sheet are substantially aligned with the markings on the substrate. The combination of Haverstock '521 and '564 teaches providing a marking on the surgery site, but the marking is not originally disposed on the proximal surface of the second portion of the release sheet. It would have been an obvious matter of design choice to initially provide the markings on the proximal surface of the second portion of the release sheet since applicant has not disclosed that doing so provides any advantage over placing markings directly on the surgery site, and it appears that the combination of Haverstock '521 and '564 performs the task of aligning the wound after surgery and approximating the tissue equally well as that of the present application.

Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Haverstock '521 and '564 as applied to claim 1 above, and further in view of Baker et al. (US 6742522).

The combination of Haverstock '521 and '564 teaches all limitations of preceding dependent claim 1, but fails to teach

- wherein the substrate is formed from a material selected from the group consisting of polyurethane, polyolefins, copolyesters and polyether polyamides.
- wherein the adhesive layer is formed from an adhesive material selected from the group consisting of acrylic copolymer, polyisobutylene, polyurethane, polymeric silicone and rubber-based hotmelts.
- wherein the adhesive layer or substrate comprises a sufficient quantity of an antimicrobial agent to substantially inhibit the growth of microorganisms on the skin of the patient adjacent said adhesive.

Baker teaches a surgical drape wherein the substrate (12) is formed of polyurethane, the adhesive layer is formed of polyurethane, and the adhesive layer comprises a sufficient quantity of an antimicrobial agent from the group consisting of 2,4,4'-trichloro-2'-hydroxydiphenyl ether, benzalkonium chloride, silver sulfadiazine and povidone iodine, in order to provide an elastomeric substrate and adhesive, to improve conformability when applied to a patient and prevent infection of the wound. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Haverstock '521 and '564 as taught by Baker in order to

Art Unit: 3731

provide an elastomeric substrate and adhesive, to improve conformability when applied to a patient and prevent infection of the wound.

Allowable Subject Matter

Claim 3 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 10 is allowable.

The following is a statement of reasons for the indication of allowable subject matter: The combination of Haverstock '521 and '564 fails to teach providing a secondary release sheet disposed on the proximal surface of the primary release sheet, transferring markings from the proximal surface of the second portion of the primary release sheet to the skin, prior to performing the surgical procedure.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

Art Unit: 3731

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application Nos. 10/640175 and ^{10/830948}~~10/640175~~. Although the conflicting claims are not identical, they are not patentably distinct from each other because they relate to the same inventive concept, being a surgical wound closure device having transfer markings.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
7/21/06


(JACKIE) TAN-JUEN-HO
PRIMARY EXAMINER

7/21/06